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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,722	05/01/2001	Stanley E. Katz	CSI 1.0-005CIP	8104

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EXAMINER	
MITCHELL, GREGORY W	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,722	KATZ ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-31* is/are pending in the application.

4a) Of the above claim(s) *19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-18 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed June 25, 2004, and the RCE filed February 22, 2005. Claim 1 has been amended. Claims 1-6 and 8-31 are pending. Claims 19-26 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-6, 8-18 and 27-31 are examined herein.

The rejections of the previous Office Action, dated March 23, 2005, are hereby withdrawn. The following rejections now apply.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2004 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-17 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz (USPN 5798388) in view of Amschler et al. (USPN 5449676).

Katz teaches a method of treating a disease state in mammals caused by mammalian cells involved in the inflammatory response which comprises contacting the mammalian cells involved in the inflammatory response with a therapeutically effective amount of an inflammatory mediator (col. 4, lines 58-67). The inflammatory mediators are taught to be antioxidants selected from pyruvates (including lithium pyruvate, sodium pyruvate, potassium pyruvate, etc.) and pyruvate precursors, such as pyruvyl-glycene, pyruvyl-alanine, pyruvyl-leucine, pyruvyl-valine, etc. (col. 7, lines 21-41). The inflammatory response reduced by the treatment is taught to be at least one of oxygen radical production, peroxide production, cytokine and/or protease production, prostaglandin production, erythema, histamine and interleukin production (col. 7, lines 15-20). Administration of the composition is in the form of liquids, ointments, etc. (col. 7, lines 52-56). Additional therapeutic agents, such as antibacterials, antivirals, antifungals, antihistamines, proteins, enzymes, hormones, nonsteroidal anti-inflammatories, cytokines and steroids, are taught to be administer prior to, after and/or with the inflammatory mediator (col. 8, lines 13-18). It is noted that while administration is taught for "injured cells" in general, the reference specifically teaches inhalation treatments for disorders such as bronchial asthma, bronchitis, etc. (col. 6, line 66-col. 7, line 10; col. 7, line 65-col. 8, line 12). Katz does not specifically teach the administration

of the composition to the nasal cells nor does Katz specifically teach the concentration of inflammatory mediator as herein claimed.

Amschler et al. teaches a method of treating inflammatory disorders of the lung (e.g. bronchitis, bronchial asthma, etc.) and inflammatory disorders of the nose (e.g. rhinitis, sinusitis, etc.) with an anti-inflammatory composition (col. 8, lines 36-57; col. 9, lines 61-68).

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the composition of Katz to the nasal or sinus cavities for the treatment of inflammatory disorders of the nasal or sinus cavities, such as rhinitis or sinusitis because (1) Katz teaches the treatment of mammalian cells involved in a inflammatory response with an anti-inflammatory composition, in general; (2) Katz teaches the treatment of inflammatory disorders such as bronchitis and bronchial asthma, specifically; and (3) Amschler et al. teaches that anti-inflammatory compositions are known in the art to treat inflammatory disorders of the nose, such as rhinitis and sinusitis, and that it is known in the art to treat inflammatory disorders of the lung in a similar manner to those of the nose. One would have been motivated to treat inflammatory disorders of the nose in the manner disclosed by Katz because of an expectation of success in treating a specific inflammatory disorder in a manner taught to be beneficial, generally, by Katz.

It would have been obvious to one of ordinary skill in the art to utilize the concentration of inflammatory mediator in a formulation as instantly claimed because Katz teaches the administration thereof in general and teaches that a formulation should

comprise a therapeutically effective amount. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katz and Amschler et al. as applied to claims 1-6, 8-17 and 31 above, and further in view of Geria (USPN 5478565).

Katz and Amschler et al. apply as disclosed above. The references lack a specific teaching of oxymetazoline.

Geria teaches that oxymetazoline is known for the treatment of rhinitis and sinusitis, particularly with the congestion associated therewith (col. 4, lines 1-15).

It would have been obvious to one of ordinary skill in the art to utilize oxymetazoline as the optional therapeutic agent of Katz because (1) Katz teaches that additional therapeutic agents may be utilized in addition to the inflammatory modulators disclosed therein; (2) the combined references render a treatment of rhinitis or sinusitis obvious; (3) oxymetazoline is taught by Geria as known in the art to be useful for the treatment of both rhinitis and sinusitis; and (4) "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior

art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It is noted that the skilled artisan would have been further motivated to add the oxymetazoline to the treatment of the combined references because of an expectation of success of providing, in addition to the reduction of the inflammatory response effectuated by the inflammatory modulator of Katz, congestion relief to the patient suffering from sinusitis or rhinitis.

Claim 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz and Amschler et al. as applied to claims 1-6, 8-17 and 31 above, and further in view of Picciano (USPN 5897872).

Katz and Amschler et al. apply as disclosed above. The references lack a specific teaching of the preferred solution formulation.

Picciano teaches the treatment of sinusitis with an isotonic buffered nasal saline solution comprising water, sodium chloride, 0.65% by weight, iodine, buffer and a preservative (col. 4, lines 52-59). Sodium bicarbonate, disodium phosphate/sodium phosphate and monobasic potassium phosphate/sodium hydroxide are taught as buffers (col. 4, lines 62-65). Phenylcarbinol, benzalkonium chloride and thimerosal are taught as preservatives (col. 4, lines 65-67). The solution is taught to alleviate congestion and to provide moisturization (col. 4, lines 52-59).

It would have been obvious to one of ordinary skill in the art to treat a patient suffering from sinusitis with the inflammatory modulators of the combined references in

the solution of Picciano because (1) Katz teaches the formulation of the compositions disclosed therein as formulated in solutions, in general; (2) the combined references render a method of treating sinusitis with inflammatory modulator compositions obvious; (3) Picciano teaches a solution which is, itself, useful for treating sinusitis; and (4) "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It is noted that the skilled artisan would have been further motivated to ~~add~~ utilize the solution of Picciano as the solution for the administration of the inflammatory modulators of the combined references because of an expectation of success of providing, in addition to the reduction of the inflammatory response effectuated by the inflammatory modulator of Katz, both congestion relief and nasal moisturization to the patient suffering from sinusitis.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-18 and 27-31 have been considered but are moot in view of the new ground(s) of rejection. Examiner addresses Applicant's arguments as they pertain to the instant rejections below.

Examiner does not understand Applicant's assertion: "Applicant's wish to note that they are unaware of any attempts by Examiner to obtain prior art references."

Applicant argues, "Katz teaches the use of pyruvate in lungs and does not teach the use of pyruvate for all cavities." This argument is not persuasive for the reasons set forth above. In particular, it is noted that the teaching of Katz is not limited to the treatment of lung cells. It is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to a person of ordinary skill in the art. *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966); *In re Lamberti*, 545 F.2d 747, 19USPQ 279 (CCPA 1976); *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). Furthermore, it is noted that Examiner has relied on Amschler et al. to show that anti-inflammatory treatments of inflammatory disorders of the lung are also known in the art to be useful for inflammatory disorders of the nose.

Applicant asserts, "Pyruvate acts differently in nasal cavities than in lungs." This argument is not persuasive. For the reasons set forth above, Examiner has established, absent a showing of unexpected results, that it would have been obvious to one of ordinary skill in the art to treat nasal inflammatory disorders. Furthermore, the reasons set forth for alleging that pyruvate acts differently in the nasal cavities than in the lungs is not persuasive. Examiner does not understand how the difference in the amount of nitric oxide being produced in the nasal cavity and the lungs is relevant to either the mode of operation, the efficacy of the methods or the obviousness of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER